K063714

TDI
BRINGING INNOVATION

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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JAN 3 1 2007

Date Prepared:	April 2006
Trade Name:	AXCEL FLOW
Common Name:	Dental Restorative Composite
Classification Name:	Tooth Shade Resin Material (per 21 CFR § 872.3690)
Predicate Devices:	AXCEL Restorative Composite (K051931) Kerr Corporation Revolution 2 (K013647)

Device Description

AXCEL FLOW is a visible light cure resin-based flowable restorative dental composite material, comprised of a Bis-GMA based resin, barium glass filler and fumed silica, suitable for class III, class IV and class V restorations. It utilizes the same resin components found in AXCEL restorative composite. The cured product has high strength and a high surface luster.

Intended Use

The intended use of AXCEL FLOW is for a base/liner under direct restorations and as a restoration of minimally invasive cavity preparations (including occlusal pits and fissures)

Substantial Equivalence

AXCEL FLOW is a low viscosity version of its predicate device, AXCEL restorative composite (K051931). All the resin components of AXCEL FLOW are the same as AXCEL. This is further validated by the comparative bench test conducted; diametral strength, flexural strength, Young's modulus, shrinkage, and hardness. AXCEL restorative composite (K051931) has been tested for cytotoxicity, mutagenicity, Kligman miximization test, and Implantation test and were found to be non-cytotoxic and non-mutagenic. Based on the biocompatibility testing data and all the components in AXCEL FLOW, the prior use of the same components in legally marketed predicate devices and on performance data, we believe AXCEL FLOW is safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Linda Nguyen
Regulatory Affairs Specialist
Tri Dental Innovators
13902 West Street
Garden Grove, California 92843

JAN 3 1 2007

Re: K063714
Trade/Device Name: AXCEL FLOW
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 12, 2006
Received: December 14, 2006

Dear Ms. Nguyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

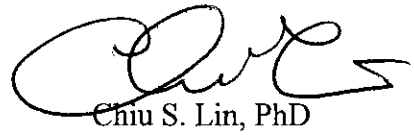
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
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Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K06 3714

Device Name: AXCEL FLOW

Indications For Use:

* Restoration of minimally invasive cavity preparations (including occlusal pits and fissures)
* Conservative anterior restorations (Classes III and IV)
* Base/liner under direct restorations
* Repair of fillings and veneers

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) K063714